

REMARKS

Status of Claims

Claims 1, 12 and 22 are amended and claims 10, 13 and 15 are cancelled without prejudice to future prosecution. Therefore, with entry of this amendments, claims 1 to 9, 11, 12, and 14 to 23 are pending.

Claims 1, 12, and 22 have been amended to specify that the milk sample is a crude milk sample. Support for use of a crude milk sample is provided, for example, in original claims 2 and 13; at page 5, lines 10-11; at page 6, lines 4-12; and at page 11, lines 7-8. Claim 1 has also been amended to include the limitations of original claim 10. Claims 1 and 22 has been further amended to specify that the detectable DNA probe is a fluorescent label, as set forth in the specification, for example, at page 8, line 29 to page 10, line 28. Finally, claim 12 has been amended to include a fluorescent label, which is supported, for example, 15 and at page 8, line 29 to page 10, line 28.

Therefore, no new matter is added with entry of this amendment.

Claim Rejection under 35 U.S.C. § 112

Claims 1 to 9 and 11 stand rejected as allegedly incomplete for omitting essential steps. The rejection refers to 35 U.S.C. § 112, first paragraph as well as MPEP § 2172.01. Applicants note that MPEP § 2172.01 cites *In re Mayhew* 527 F.2d 1229 (CCPA 1229) for the proposition that a "claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, first paragraph, as **not enabling**." See MPEP § 2172.01 (emphasis added); see also *In re Mayhew* at 1231 ("Although the examiner failed to specify what paragraph of § 112 he was relying on —the better practice being to so specify in order to comply fully with the spirit of § 112—it is clear that he was relying on § 112, paragraph one, which requires that claims be supported by an enabling disclosure." (emphasis added)). Therefore, Applicants assume that the rejection was intended to assert that claims 1 to 9 and 11 are non-enabled.

Applicants respectfully disagree that claims 1 to 9 and 11 as filed are non-enabled. One of skill in the art would easily be able to detect DNA by following the teachings of the specification. For example, Applicants provide extensive teachings on methods of detecting DNA in a milk sample at page 8, line 24, to page 10, line 28. Moreover, Examples 1, 2, and 3 recite DNA detection methods in detail. The provisions of § 112, first paragraph require no more.

In the interest of expediting prosecution, however, Applicants have amended claim 1 to include the elements of claim 10 as filed. Applicants note that claim 10 was not included in the § 112 rejection and thus are presumably viewed as containing all essential elements. Therefore, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 112.

Claim Rejection under § 102(b)

Claims 1 to 23 stand rejected as allegedly anticipated under 35 U.S.C. § 102(b) in view of Alatossava et al. (USP 5,849,488). Applicants respectfully assert that the claims as amended are not anticipated by Alatossava et al.

Claim 1 as amended specifies that the milk sample is a crude milk sample that is contacted with a fluorescent label for detection of DNA in the crude milk sample. Applicants' specification states: "'A crude milk sample' is a milk sample in which the milk fat is not removed from the raw sample (e.g. by centrifugation).'" See page 5, lines 10-11. One embodiment of the method set forth in amended claim 1 is described in Example 1. In method three of Example 1, no centrifugation is performed to remove fat from the milk sample. Rather, the crude milk sample is contacted directly with a fluorescent label and the amount of DNA is detected directly from the crude milk sample. Thus, claim 1 does not encompass methods in which detection of the fluorescent label is performed after isolation of the DNA from the milk sample.

In contrast, Alatossava et al. sets forth methods that require isolation of DNA before detection of the DNA using PCR based techniques. Alatossava et al. state:

In summary, for the purpose of a mastitis diagnosis both the infection study and the inflammation study can be

performed by PCR with specific primer pairs simultaneously **after DNA from the mastitis milk sample has been isolated** using relatively simple and rapid procedures as shown in examples 6 and 7.

See Alatossava et al. at Column 6, lines 58-63 (emphasis added). Moreover, Alatossava et al. fail to disclose any methods of detecting DNA using fluorescent probes. Therefore, Alatossava et al. fail to disclose a method including the steps of "contacting said crude milk sample with a fluorescent label" and "detecting said DNA fluorescent label in said crude milk sample thereby detecting the DNA in said crude milk sample."

With respect to Claim 12, Alatossava et al. fail to disclose an analytical composition "comprising a crude milk sample, a metal ion chelator, a fluorescent label, and a detergent." And with respect to Claim 22, Alatossava et al. fail to disclose a "kit for detecting a nucleic acid in a crude milk sample comprising a metal ion chelator, a detergent, and a fluorescent label."

Because Alatossava et al. fail to disclose all the elements of claims 1 to 23 as amended, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 102(b).

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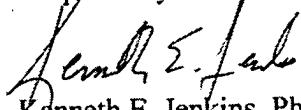
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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 858-350-6100.

Respectfully submitted,


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